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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,859	12/20/2001	J. Michael Ramstack	000166.0108-US01	1415

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EXAMINER	
VENKAT, JYOTHSNA A	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/022,859	RAMSTACK ET AL.	
	Examiner	Art Unit	
	JYOTHSNA A. VENKAT Ph. D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *65,75-81,83,86-88,94,95,99,101,102 and 116-118* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *65,75-78,80-81,83,86, 88,94,95,99,101,102 and 116-118* is/are rejected.

7)☒ Claim(s) *79 and 87* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 8/29/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of amendment, remarks and IDS filed on 8/29/06. Claims 66-74, 82, 84-85, 89-93, 96-98, 100, and 103-115 have been canceled as per applicant's amendment dated 8/29/06. Claims 65, 75-81, 83, 86-88, 94-95, 99, 101-102 and 116-118 are pending in the application and the status of the application is as follows:

In view of amendment to the claims, the 112, rejection is modified.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 65, 75-78, 80-81, 83, 86, 88, 94-95, 99, 101-102 and 116-118 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for flowability of microparticles by conditioning the microparticles using the active ingredient Risperidone for wherein conditioning is at a temperature of about 25 degrees Celsius and angle of repose of 21.3 and 23.7 and the number of days being 5 or 6 days and angle of repose being 21.8 or 18.4 does not reasonably provide enablement for flowability of the particles using any temperature or any active ingredient or any number of days (note that at least 5 days can be minimum 5 days and maximum can be any number of days). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement

and whether any necessary experimentation is " *undue* ". See ***In re Wands, 858 F.2d 731, 737, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1998).*** The court set forth the eight factors to consider when assessing if a disclosure would require undue experimentation. Citing *Ex parte Forman, 230 USPQ 546*, the court recited eight factors

These factors include, but are not limited to:

1*) The breadth of the claims,*

2) The nature of the invention,

3) The state of the prior art,

4) The level of one of ordinary skill,

5) The level of predictability in the art,

6) The amount of direction provided by the inventor,

7) The existence of working examples

8) The quantity of experimentation needed to male or use the invention based on the content of the disclosure.

(1 and 2) The breadth of the claims and the nature of the invention: The claims are drawn method for processing the microparticles to improve the flowability. This is claimed independently in claims 65, 80, 94, 116 and 117.

(3 and 5) The state of the prior art and the level of predictability in the art: See article by Prescott drawn to " on powder flowability", submitted by applicants. The art teaches that "powder flow is complex" at page 60. Attention is drawn to page 60 where the article teaches that "*flow dimension is multi dimensional and does in fact depend on many powder characteristics and for this reason no one test could quantify flowability*". The article at page 60

also teaches "*flowability can never be expressed as a single value or index*" Applicants attention is also drawn to page 62, where it states that "*no universal mathematical model exists to predict powder flow behavior*". Thus the art is highly unpredictable and complex.

(6-7) The amount of direction provided by the inventors and the existence of working examples: applicants at page 10 admit that the micro particles are conditioned according to the process disclosed in patent 5,650,173 and state that the conditioned process is carried out in closed container with dry product and the testing is done using Risperidone and Table 1 showed that treatment of Risperidone particles which was sifted and kept at 72 degrees F for 1 week had excellent flowability and this was due to the angle of repose being 21.3 or 23.7. Applicants admit at page 13, that the flowability of the micro particles improved from good to excellent by maintaining the micro particles for one week at 72 degrees F for one week. There is no other data, which showed that excellent flowability was obtained using any active ingredient or any temperature or any angle of repose. See also table 2 where in the Risperidone micro particles had excellent flowability when the temperature was maintained between 20-25 degrees C and kept for 5-6 days at this temperature. The angle of repose was 21.8 and 18.4. Thus angle of repose appears to play critical role and this is accomplished using specific conditions. Applicants admit at last line of page 13 that improved flowability is characterized by a decrease in the angle of repose". See also table 3 where angle of reposes plays critical role with the specific processes. The specification at page 22 teaches various parameters and the flowability index. The angle of repose in table 7 is greater than the value obtained in tables 1 and 2. According to the article by Prescott there is "*no universal mathematical model exists to predict powder flow behavior*". *The specification does not show the nexus between the flowability indexes and flow property and*

angle of repose. Applicants are relying on Carr's parameters and the article was published in 1965 (see page 20) where as the article by Prescott in 2000 states "there is no mathematical model exits to predict powder flow behavior".

(8) The quantity of experimentation needed to make or use the invention bases on the content of the disclosure: The claims are drawn method for processing the microparticles to improve the flowability. This is claimed independently in claims 65, 80, 94, 114, 116 and 117 and the claims recite no specific angle of repose or specific temperature or time or active ingredient. See the article by Prescott, which clearly states that powder flow is complex phenomena and in view of the complexity and unpredictability, the instant specification gives one skilled in the art no indication that the one could use the claims without the specific parameters tested in the specification and have a reasonable expectation of success. The instant specification also gives no guidance that the flowability of the microparticles was obtained using the flow index greater than about 60 and the angle of repose is greater than the value tested in tables 1-2 and the specification does not show the nexus between the three parameters, which are angle of repose, flowability index and flow property (emphasis added). Therefore further testing would be necessary to use the claimed invention and the practice of the full scope of the invention would require undue experimentation.

Response to Arguments

Applicant's arguments filed 8/29/06 have been fully considered but they are not persuasive.

The gist of applicants arguments with respect to all the wands factors are that table 7 presented data showing that a flowability index greater than about 60 was obtained for

conditioned microparticles maintained at 25 degrees Celsius and a period of at least 5 days and independent claims 65, 80, and 94 explicitly recite conditioning the microparticles by maintaining the microparticles at a conditioning temperature of about 25°C for a period of at least about 5 days and independent claims 116 and 117 explicitly recite conditioning the microparticles for at least about 5 days at a conditioning temperature that is less than a glass transition temperature (Tg) of the polymer since table 7 provides the Carr parameters, the flowability index, and the Tg (glass transition temperature) for placebo microparticles (those containing no active agent), as well as microparticles containing the active agent Risperidone and therefore the specification enables one skilled in the art to practise the methods recited in the claims.

In response to the above argument, applicants attention is drawn to table 7 wherein the flowability index is based upon the four parameters namely angle of repose, angle of spatula, cohesion and compressibility. These 4 Carr parameters determine the flowability index. The time period is at least 5 days. Claims 116 and 117 do not recite the specific period and the 4 Carr parameters that determine the flowability index.

With respect to claims 65, 80 and 94 applicant's attention is drawn to table 3. The specification at page 13 states "Exposing the placebo microparticles (Batch D) to dry air at ambient temperature for 15 days was insufficient to improve flowability. **However, improvement in flowability in these microparticles was observed after exposure to 45°C for 10 days**. The degradation in 5 flowability of placebo microparticles resulting separately from vacuum and tumbling can be seen in the Batch E data in Table 3." Thus the results clearly demonstrate that flowability was obtained for placebo **after exposure to 45 degrees and time**

period for 10 days. It is the position of the examiner that microparticles having improved flowability was obtained for Risperidone by conditioning at 25 degrees Celsius and time period is 5-6 days and not for any active ingredient. Therefore further testing would be necessary to use the claimed invention and the practice of the full scope of the invention would require undue experimentation.

Allowable Subject Matter

Claims 79 and 87 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A. VENKAT Ph. D whose telephone number is

571-272-0607. The examiner can normally be reached on Monday-Friday, 10:30-7:30:1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JYOTHSNA A VENKAT Ph. D
Primary Examiner
Art Unit 1615

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